MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100593-PIP01-22

Scope of the Application

Active Substance(s)

aticaprant

Condition(s)

Treatment of Major Depressive Disorder

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Janssen-Cilag Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag Limited submitted to the licensing authority on 16/06/2023 18:23 BST an application for a Paediatric Investigation Plan

The procedure started on 23/10/2023 09:12 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100593-PIP01-22

Of 03/11/2023 16:44 GMT

On the adopted decision for aticaprant (MHRA-100593-PIP01-22) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for aticaprant, Film-coated tablet , ORAL USE .

This decision is addressed to Janssen-Cilag Limited, 50-100 Holmers Way, High Wycombe, UNITED KINGDOM, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of major depressive disorder The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 7 years of age Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of major depressive disorder

2.2 Indication(s) targeted by the PIP:

Adjunctive treatment of major depressive disorder (MDD) in paediatric patients who have responded inadequately to antidepressant (SSRI) medication and psychotherapy

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 7 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Acceptability and tolerability of the 5 mg film-coated tablet in the target population.
Non-Clinical Studies	1	Study 2 Definitive juvenile toxicity study.
Clinical Studies	2	Study 3 An 8-week, multicentre, double blind, randomised, parallel-group, placebo-controlled study followed by a long-term (52-week), open-label extension study to evaluate the PK, efficacy and safety of aticaprant as adjunctive therapy to antidepressants in children and adolescents from 7 years to less than 18 years with major depressive disorders with anhedonia who have responded inadequately to SSRI monotherapy. Study 4 An 8-week, multicentre, double-blind, randomised, parallel-group, placebo controlled study followed by a long-term (44-week), double-blind, placebo-controlled extension study to evaluate the PK, efficacy and safety of aticaprant as adjunctive therapy to antidepressants in children and adolescent participants from 7 years to less than 18 years with major depressive disorder with anhedonia who have responded inadequately to SSRI monotherapy.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Population PK model for dose finding. Study 6 Population

		PK model for extrapolation / interpolation.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/09/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes